Supreme Court, U.S.
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No.

In the Supreme Court of the United States

OCTOBER TERM, 1996

DAVID A. KESSLER, M.D.,
COMMISSIONER OF FOOD AND DRUGS, AND
BRUCE A. LEHMAN, ASSISTANT SECRETARY OF
COMMERCE AND COMMISSIONER OF PATENT AND
TRADEMARKS, CROSS-PETITIONERS

v.

ORGANON, INC., BRACCO DIAGNOSTICS INC. AND
BRACCO INTERNATIONAL B.V., ET AL.

*ON PETITION FOR A WRIT OF CERTIORARI
TO THE UNITED STATES COURT OF APPEALS
FOR THE FEDERAL CIRCUIT*

CROSS-PETITION FOR A WRIT OF CERTIORARI

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QUESTION PRESENTED

The 1994 Uruguay Round Agreements Act (URAA) establishes a new patent term of 20 years from the date on which the patent application was filed. 35 U.S.C. 154(a)(2). The transitional provision of the URAA provides that "[t]he term of a patent that is in force on or that results from an application filed before [June 8, 1995] shall be the greater of the 20-year term as provided in subsection (a) or 17 years from grant, subject to any terminal disclaimers." 35 U.S.C. 154(c)(1).

The question presented by this petition is whether the court of appeals erred in declining to uphold the determination of the Commissioner of Patents and Trademarks that, with respect to patents affected by the transitional provision of the Uruguay Round Agreements Act (URAA), 35 U.S.C. 154(c)(1), extensions granted under the Hatch-Waxman Act, 35 U.S.C. 156, cannot be added to the URAA's newly-created 20-year patent term.

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In the Supreme Court of the United States

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No.

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FOR THE FEDERAL CIRCUIT

CROSS-PETITION FOR A WRIT OF CERTIORARI

The Solicitor General, on behalf of David A. Kessler, M.D., Commissioner of Food and Drugs, and Bruce A. Lehman, Assistant Secretary of Commerce and Commissioner of Patents and Trademarks, respectfully conditionally cross-petitions for a writ of certiorari to review the judgment of the United States Court of Appeals for the Federal Circuit in this case. If the Court grants the petition in either

No. 96-562 or 96-575, it also should grant this petition. If the Court denies both of those petitions, this cross-petition also should be denied.

OPINIONS BELOW

The opinion of the court of appeals (Pet. App. 1a-23a)[1] is reported at 80 F.3d 1543. The opinion of the district court in No. 96-575 (Pet. App. 28a-39a) is reported at 903 F. Supp. 964. The opinion of the district court in No. 96-562 (Pet. App. 24a-27a) is unreported. The district court's orders on remand from the court of appeals' decision (Pet. App. 40a-41a; 96-575 Pet. App. 29a-34a) are unreported.

JURISDICTION

The judgment of the court of appeals (Pet. App. 92a-94a) was entered on April 4, 1996, and its mandate was issued on July 19, 1996. The federal parties' petition for rehearing was denied on July 12, 1996. Pet. App. 80a-91a. A petition for a writ of certiorari was filed by Organon, Inc. (No. 96-562) on October 9, 1996, and was placed on this Court's docket on the same day. A petition for a writ of certiorari was filed by Bracco Diagnostics Inc. and Bracco International B.V. (No. 96-575) on October 10, 1996, and was placed on this Court's docket on October 15, 1996. This conditional cross-petition is filed pursuant to Rule 12.5 of this Court. The jurisdiction of this Court is invoked under 28 U.S.C. 1254(1).

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[1] Unless otherwise indicated, Pet. App. refers to the Appendix in No. 96-562.

STATEMENT

The facts and proceedings are set forth in the brief in opposition of the federal parties filed in Nos. 96-562 and 96-575.

REASONS FOR GRANTING THE CROSS-PETITION

As explained in the brief in opposition of the federal parties filed in Nos. 96-562 and 96-575, this case does not present issues of sufficient public importance to warrant this Court's review. The case involves a transitional provision of the URAA, and thus has only a temporally limited significance.

If this Court were to grant the petition in either No. 96-562 or 96-575, however, its review of the questions presented in either or both of those petitions also should encompass the error of the court of appeals in failing to defer to the reasonable interpretation of the Commissioner of Patents and Trademarks concerning the availability of patent term extensions to transition period patent holders. As set forth in the PTO's Final Determination (Pet. App. 56a-66a), the Commissioner, after notice and comment, determined that, with respect to patents in force on, or that resulted from an application filed before, June 8, 1995 (the effective date of the URAA), extensions granted under the Hatch-Waxman Act, 35 U.S.C. 156, could be added only to the original term of 17 years from the date of the patent's issuance, and not to URAA's newly created 20-year patent term. Under PTO's decision, a transition period patent holder is entitled to the greater of (i) 17 years from the date of the patent's issuance plus the Hatch-Waxman extension or (ii) a term of 20 years from the date of the patent application.

The court of appeals acknowledged that "Congress did not expressly address the question whether a restoration extension under section 156 could be added to the term of a patent which could also invoke the section 154 transitional provision." Pet. App. 8a. In declining to defer to PTO's Final Determination, the court of appeals acted contrary to this Court's repeated admonition that "if the statute is silent or ambiguous with respect to the specific issue, the question for the court is whether the agency's answer is based on a permissible construction of the statute." *Chevron U.S.A. Inc.* v. *Natural Resources Defense Council, Inc.*, 467 U.S. 837, 843 (1984).

The court of appeals justified its refusal to accord *Chevron* deference to PTO's statutory interpretation because "Congress has not vested the Commissioner with any general substantive rulemaking power." Pet. App. 13a-14a. That reasoning is contrary to this Court's decisions requiring deference to an agency's reasonable interpretation of a statute that the agency administers or enforces. See *Clarke* v. *Securities Indus. Ass'n*, 479 U.S. 388, 403 (1971) ("It is settled that courts should give great weight to any reasonable construction of a regulatory statute adopted by the agency charged with enforcement of that statute.") (quoting *Investment Co. Institute* v. *Camp*, 401 U.S. 617, 626 (1971)); see also *Smiley* v. *Citibank (South Dakota), N.A.*, 116 S. Ct. 1730, 1733 (1996) ("It is our practice to defer to the reasonable judgments of agencies with regard to the meaning of ambiguous terms in statutes that they are charged with administering."); *NationsBank of North Carolina, N.A.* v. *Variable Annuity Life Ins. Co.*, 115 S. Ct. 810, 813 (1995) (*Chevron* deference given to Comptroller of the Currency's interpretation of a statute

the agency administered and applied in an adjudication).[2] The court of appeals' failure to accord proper deference to PTO's Final Determination led to an erroneous interpretation of the statute and to a result not advocated by any of the parties to this case.

1. Congress has declared that "[t]he Commissioner [of the Patent and Trademark Office] * * * shall superintend or perform all duties required by law respecting the granting and issuing of patents." 35 U.S.C. 6(a). Under that grant of authority, PTO promulgated its Final Determination to carry out its statutory duty to determine whether patent holders

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[2] Moreover, the court of appeals' refusal to defer to the PTO's Final Determination conflicts with many court of appeals' decisions that defer to an agency's reasonable interpretation of a statute it administers. See, *e.g.*, *Wagner Seed Co.* v. *Bush*, 946 F.2d 918, 922 (D.C. Cir. 1991) ("it simply is not the law of this circuit that an interpretive regulation does not receive the *Chevron* deference accorded a legislative regulation"), cert. denied, 503 U.S. 970 (1992); *Midtec Paper Corp.* v. *United States*, 857 F.2d 1487, 1496-1497) (D.C. Cir. 1988) (deference due to a permissible agency interpretation whether it arises out of rulemaking or adjudication); *American Land Title Ass'n* v. *Clarke*, 968 F.2d 150, 154 (2d Cir. 1992) (rejecting argument that pronouncement of Office of Comptroller of the Currency is not entitled to deference because it took the form of an interpretive rule rather than a legislative regulation), cert. denied, 508 U.S. 971 (1993); *Kennedy* v. *Shalala*, 995 F.2d 28, 30 n.3 (4th Cir. 1993) ("[t]hough the interpretive ruling at issue here does not itself have the force and effect of law or regulation, it is nonetheless entitled to deference as the Secretary's interpretation of a statute she is charged with administering"); *Satellite Broadcasting & Communications Ass'n of America* v. *Oman*, 17 F.3d 344 (11th Cir.) (Copyright Office's interpretive rules upheld as not arbitrary, capricious, or in conflict with the clear meaning of the statute), cert. denied, 115 S. Ct. 88 (1994).

affected by the transitional provisions of the URAA are entitled to Hatch-Waxman extensions. When a patent holder submits an application for a Hatch-Waxman Act extension, the Commissioner must determine the length of that extension. 35 U.S.C. 156(c) and (e). In making that determination, the Commissioner must ensure that the extension, when added to the period remaining in the term of the patent, does not exceed 14 years from the date of FDA approval of the drug. 35 U.S.C. 156(c)(3). Accordingly, for a transitional patent holder, the Commissioner necessarily must ascertain eligibility for, and length of, an extension by first determining whether the extension is added to the 17-year-from-grant term or the 20-year-from-application term.[3] Hence, in concluding that for transitional patent holders a Hatch-Waxman Act extension may be added only to the 17-year term, PTO's Final Determination interpreted legal provisions that PTO necessarily must apply in carrying out the statutory duties that Congress entrusted to the agency.[4]

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[3] Other determinations that PTO must make in granting extensions under Section 156 include: (1) whether the patent has expired (35 U.S.C. 156(a)); (2) whether the patent has previously been extended under Section 156(e) (35 U.S.C. 156(a)); (3) whether the product has been subject to a regulatory review period before its commercial marketing or use (35 U.S.C. 156(a)); (4) whether the application for the extension was submitted within 60 days of the date on which the product received permission for commercial marketing or use (35 U.S.C. 156(d)(1)); and (5) whether the patent is eligible for an extension (35 U.S.C. 156(e)).

[4] The expiration date of a patent term relates to other statutory duties of the PTO, including its obligation to determine (1) whether to initiate an interference proceeding (35 U.S.C. 135 ("[w]henever an application is made for a patent

2. Under *Chevron*, 467 U.S. at 843, courts are required to defer to an agency's reasonable construction of a statute that it administers if Congress has not addressed the precise question at issue. Although it is undisputed that "Congress did not expressly address the question" at issue in this case (Pet. App. 8a), the court of appeals refused to accord deference to PTO's interpretation because PTO has no rulemaking authority. Pet. App. 13a-14a.[5]

The court of appeals' ruling is based on the notion that because PTO's Final Determination is an interpretive rather than a legislative rule, the statutory construction issue may be decided *de novo*.[6] That rationale finds support in *EEOC* v. *Arabian American Oil Co.*, 499 U.S. 244 (1991), in which the Court concluded that because Congress did not confer

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which, in the opinion of the Commissioner, would interfere with any pending application, or with *any unexpired patent*, an interference may be declared") (emphasis added)); (2) whether a patent is eligible for reexamination (37 C.F.R. 1.510(a)); and (3) whether a patent is eligible for reissuance (*In re Morgan*, 990 F.2d 1230 (Fed. Cir. 1993) (under 35 U.S.C. 251, the Commissioner cannot reissue a patent whose term has expired)).

[5] The district court concluded that no deference was due to the PTO in "a straightforward matter of statutory interpretation." Pet. App. 34a. This Court specifically has rejected, however, the proposition that *Chevron* deference is inapplicable to "a pure question of statutory construction." *NLRB* v. *United Food & Commercial Workers Union*, 484 U.S. 112, 123 (1987).

[6] The court relied on earlier precedent that PTO's authority under 35 U.S.C. 6(a) to "establish regulations, not inconsistent with law, for the conduct of proceedings in the Patent and Trademark Office" did not grant PTO "the authority to issue substantive rules." Pet. App. 13a.

upon the EEOC authority to promulgate rules and regulations, "the level of deference afforded 'will depend upon * * * all those factors which give [the agency] power to persuade, if lacking power to control.'" 499 U.S. at 257 (quoting *Skidmore* v. *Swift & Co.*, 323 U.S. 134, 140 (1944)). In his concurring opinion, Justice Scalia expressed the view that "the 'legislative rules vs. other action' dichotomy" is an "anachronism" "[i]n an era when our treatment of agency positions is governed by *Chevron*." 499 U.S. at 260 (Scalia, J., concurring). Indeed, this Court's recent unanimous decision in *NationsBank of North Carolina, N.A.* v. *Variable Annuity Life Ins. Co.*, *supra*, applied *Chevron* deference to an agency adjudication and held that "[i]f the administrator's reading fills a gap or defines a term in a way that is reasonable in light of the legislature's revealed design, we give the administrator's judgment 'controlling weight.'" 115 S. Ct. at 813-814.[7] The Court has long applied a similar approach to interpretations of the agency's governing statute adopted in the course of adjudications by the National Labor Relations Board, which has seldom utilized its rulemaking authority. See, *e.g.*, *NLRB* v. *Town & Country Elec., Inc.*, 116 S. Ct. 450, 453 (1995). We sub-

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[7] Even the case upon which the court of appeals primarily relies—*Atchison, T. & S. F. Ry.* v. *Peña*, 44 F.3d 437, 441-442 (7th Cir. 1994) (en banc), aff'd, 116 S. Ct. 595 (1996)—gave "weight" to the Federal Railroad Administration's interpretive rule. Moreover, in that case the agency abandoned its long-established interpretation of a statute, and, to promote uniformity, adopted the interpretation given to the statute by the Ninth Circuit, even though the agency disagreed with that ruling. In those circumstances, which are not present here, the court declined to give *Chevron* deference to the agency's rule.

mit that, as an interpretative application of governing legal provisions charged to the agency's administration, PTO's Final Determination in this case is similarly entitled to substantial weight. Congress has not addressed the "combined effects of the URAA and the Hatch-Waxman Act for patents issued prior to June 8, 1995." Pet. App. 8a. PTO's Final Determination addresses that question and reasonably interprets those two statutes.

3. According due deference, the court of appeals should have accepted the statutory interpretation set forth in PTO's Final Determination. Under Section 156 of the Hatch-Waxman Act, extensions run "from the original expiration date of the patent." 35 U.S.C. 156(a). That term is not defined in the statute. PTO's determination that it means the "date on which the patent, *when granted*, was set to expire" (Pet. App. 59a (emphasis added)) is reasonable and in accord with the plain meaning of the statutory language. Reasonably interpreting the term "original expiration date" to describe only the end of the original 17-year from issuance term, PTO logically concluded that, for transitional patents in force on June 8, 1995, Hatch-Waxman extensions are not added to the URAA's newly created 20-year term, because the original expiration date of transitional patents is fixed at the time the patents were issued—17 years from grant—and cannot be shifted to the end of the new 20-year term.

In ruling *de novo* that the term "original expiration date" means "no more than that the expiration date has not been extended under section 156(e)(1) and, thus, the phrase can identify more than one date" (Pet. App. 17a), the court of appeals relies on a letter from Congressman Tom Railsback for the proposition

that the phrase "original expiration date" simply ensures that a patent does not receive a second Hatch-Waxman extension. That letter, however, does not address the specific provision at issue, but addresses a bill that was not enacted into law and that did not contain the current provision of the Hatch-Waxman Act that allows patent extensions only if "the term of the patent has never been extended under subsection (e)(1) of this section." 35 U.S.C. 156(a)(2). The current language makes the interpretation reflected in the Railsback letter superfluous.[8]

Finally, PTO's ruling reconciles and fully effectuates the two statutory provisions at issue while avoiding problems created by the court of appeals' decision. For example, the court of appeals recognized that under its interpretation, "[i]n some instances, there may be a problem in adding a restoration extension granted pre-URAA to the 20-year term" because "[u]nder the Hatch-Waxman Act [Section 156(c)(3)] the patent term plus any restoration extension cannot exceed 14 years from the date of FDA approval." Pet. App. 17a-18a. Instead of

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[8] Furthermore, the court erred in relying on the URAA amendment that added to Section 156(a)(2) the phrase "under subsection (e)(1)." Pet. App. 16a-17a. Prior to that amendment, Section 156(a)(2) required that "the term of the patent had never been extended" in order for the patent to be eligible for an extension under Section 156. Because the URAA added new extensions to account for delays in the issuance of a patent due to a successful appeal of adverse PTO decisions or for delays caused by patent interference proceedings, 35 U.S.C. 154(b), an amendment to Section 156(a)(2) became necessary to make clear that an extension under Section 154(b) does not preclude a Hatch-Waxman extension pursuant to Section 156. The amendment to Section 156(a)(2) simply prevents that unintended result, and does not address the question at issue here.

deferring to PTO's reasonable interpretation of the statute that would have avoided that "problem" altogether, the court of appeals observed that "[c]orrection to fit within the 14-year limitation entails only a purely ministerial task." *Id.* at 18a. That approach, however, finds no support in the statute.[9]

CONCLUSION

If the Court grants the petition in No. 96-562 or 96-575, it also should grant this petition. If the Court denies both of those petitions, this cross-petition also should be denied.

Respectfully submitted.

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NOVEMBER 1996

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[9] The court of appeals also noted (Pet. App. 19a) the "[m]ore troubling * * * problem of fitting together the different limitations on remedies during successive extensions," a problem that would also be alleviated by PTO's determination that Hatch-Waxman Act extensions cannot be added to URAA's new 20-year term for transitional patents.

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Nos. 96-728, 96-761

IN THE SUPREME COURT OF THE UNITED STATES

October Term, 1996

DAVID A. KESSLER, M.D ET AL.,
ConditionalCross-Petitioners,

v.

ORGANON, INC., ET AL.,
Respondents.

GENERIC PHARMACEUTICAL INDUSTRY ASSOCIATION
Conditional Cross-Petitioner,

v.

BRACCO DIGNOSTICS INC., ET AL.,
Respondents.

On Conditional Cross-Petitions for a Writ of Certiorari to the United States Court of Appeals for the Federal Circuit

BRIEF OF RESPONDENTS MERCK & CO., INC., MSD TECHNOLOGY, L.P. and SCHERING CORPORATION IN OPPOSITION

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QUESTION PRESENTED

In 1984, Congress enacted the Hatch-Waxman Act. One part of this act, codified at 35 U.S.C. § 156, states that any patent covering a drug whose marketing is delayed because of regulatory review by the Food and Drug Administration shall receive patent term restoration to compensate for part of that regulatory delay.

In 1994, in a transitional provision in the Uruguay Round Agreements Act, 35 U.S.C. § 154(c)(1), Congress mandated that the term of any patent in force on June 8, 1995, or resulting from an application filed prior to that date, shall be the greater of 20 years from filing of the patent application or 17 years from the grant of the patent, subject to any terminal disclaimer.

The question presented by the conditional cross-petitioners in this case is whether the Court of Appeals for the Federal Circuit erred when it determined that the patent of a drug whose marketing was delayed due to FDA regulatory

review was entitled to the term of 20 years from filing of the patent application mandated by the URAA together with the patent term restoration period authorized by the Hatch-Waxman Act, subject only to the restrictions on term restoration established by the Hatch-Waxman Act.

LIST OF PARTIES

This Opposition to Petitions for Writ of Certiorari is filed on behalf of Merck & Co., Inc., MSD Technology, L.P. and Schering Corporation. The parent company, non-wholly owned subsidiaries, and affiliates of Merck & Co. that have issued shares to the public are:

Banyu Pharmaceutical Co., Limited
Banyu ASC Co., Ltd.
Nippon Merck Banyu Co.Ltd.
Prodome Quimica e Farmacaeutica Ltda.
Kronans Droghandel AB
Kiineiesto Oy Irmelinpesa
Comnet Corporation

MSD Technology, L.P. is a limited partnership, comprised of four partners, three of which are wholly-owned subsidiaries of Merck & Co., Inc. The fourth partnership interest in MSD Technology, L.P. is held by Abbey National Treasury Services, P.L.C.

The parent company, non-wholly owned subsidiaries, and affiliates of Schering Corporation that have issued shares to the public are: Schering-Plough Corporation.

Other parties to the proceedings in the United States Court of Appeals for the Federal Circuit were: Bracco Diagnostics Inc. and Bracco International B.V.; Hoffmann-La Roche Inc. and Syntex (U.S.A.) Inc.; Organon, Inc.; David A. Kessler, M.D., Commissioner of Food and Drugs; Bruce A. Lehman, Assistant Secretary of Commerce and Commissioner of Patents and Trademarks; and the Generic Pharmaceutical Industry Association.

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INDUSTRY ASSOCIATION,
ConditionalCross-Petitioner,
v.

BRACCO DIAGNOSTICS INC., ET AL.,
Respondents.

On Conditional Cross-Petitions for a Writ of Certiorari
to the United States Court of Appeals
for the Federal Circuit

BRIEF OF RESPONDENTS MERCK & CO., INC., MSD TECHNOLOGY, L.P. and SCHERING CORPORATION IN OPPOSITION

STATUTES INVOLVED

The statutory issues raised by the conditional cross-petitioners in 96-728 and 96-761 arise under the Drug, Price Competition, and Patent Term Restoration Act (the "Hatch-Waxman Act"), codified in relevant part at 35 U.S.C. §§ 156 (a) and (e).

STATEMENT OF THE CASE

The relevant facts and the proceedings below are set forth in the brief in opposition of respondents Merck & Co., Inc., MSD Technology, L.P (together "Merck") and Schering Corporation ("Schering") filed in 96-562 and 96-575.

REASONS FOR DENYING THE WRIT

These cross-petitions for writ of certiorari are conditional on the grant of the petitions in 96-562 and 96-575. The reasons for denying the petitions in those two cases are discussed at some length in the brief in opposition of respondents Merck and Schering. *See* Merck/Schering Opp. at 8-15. Additional grounds for denial are presented by the

conditional cross-petitioners themselves in their oppositions to those two petitions. *See* Fed. Opp. at 9-15; GPIA Opp. at 4-6.

To summarize, the petitions in 96-562 and 96-575 should be denied because they do not present issues of general importance and do not concern a conflict with the decisions of this Court or of any court of appeals. At least one of the arguments raised in 96-562 is not properly presented for review. Moreover, the case in 96-562 is moot.

Even if certiorari were granted in 96-562 or 96-575, however, the conditional cross-petitions should be denied. In addition to the fact that the conditional cross-petitioners themselves acknowledge that this case does not present any issue of general importance -- a point highlighted by the decision of the Solicitor General not to seek certiorari in the normal course -- cross-petitioners cannot show a substantial basis for believing that the court below erred in its interpretation of the Hatch-Waxman Act.

The interpretation of the Hatch-Waxman Act adopted by the court below is the only reading faithful to the language, history, and structure of the Hatch-Waxman Act. Federal cross-petitioners are incorrect in their assertion that the court below erred by not deferring to the "Final Determination" of the PTO, which claimed to interpret provisions of the Hatch-Waxman Act, as this is not a case where *Chevron* deference applies. Moreover, the interpretation of the Hatch-Waxman Act urged by federal cross-petitioners cannot be reconciled with the statutory language, history, and structure of the statute. Nor is there any better support in the statute for the different position taken by conditional cross-petitioner Generic Pharmaceutical Industry Association ("GPIA"), which correctly rejects the position taken by the federal cross-petitioner. *See* 96-761 Cross-Pet. at 6-7.

1. To secure review by this Court in the absence of a conflict among circuits,[1/] conditional cross-petitioners must demonstrate both that there is a substantial basis for believing that the court below erred in its construction of the governing statute and that the issue has substantive importance. *See* Sup. Ct. R. 10(c). The cross-petitioners are unable to meet this standard.

As the conditional cross-petitioners forthrightly acknowledge, this case does not present an issue of general importance. Rather, the case concerns only a transitional provision of highly attenuated significance. *See* 96-728 Cross-Pet. at 3; *see also* 96-761 Cross. Pet. at 7. Even that limited significance is being continually eroded by time, as additional patents subject to the transitional rules of 35 U.S.C. § 154(c)(1) expire. For example, as the cross-petitioners

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[1/] Cross-petitioners do not claim that this case presents a circuit split. Moreover, because the determination of issues arising under 35 U.S.C. § 156 are within the exclusive jurisdiction of the Federal Circuit under 28 U.S.C. §1295(a)(1), there could not be a conflict among the circuits on the issues presented here.

pointed out in their briefs in opposition in 96-562 and 96-575, the passage of time has already made the case in 96-562 moot. *See* Fed. Opp. at 9; GPIA Opp. at 2.

2. Nor can the conditional cross-petitioners show a substantial basis for believing that the court below erred in its construction of the governing statute. None of the cross-petitioners challenge the Federal Circuit's holding that all of the patents in issue were in force on June 8, 1995, *see* 35 U.S.C. § 154(c)(1), which is the only issue decided below that required an interpretation of the Uruguay Round Agreements Act ("URAA"). Thus, the only issue of law raised by the cross-petitioners is whether the Federal Circuit correctly interpreted the Hatch-Waxman Act. On that latter point, the holding of the Federal Circuit relies on an interpretation of the Hatch-Waxman Act that, unlike those proposed by the conditional cross-petitioners, conforms with the mandatory language of the statute and is equally supported by the history and structure of the Act.

In the URAA, Congress changed the terms of patents from 17 years from grant of the patent to 20 years from filing of the patent application. Transitional provisions incorporated in the URAA require that the term of patents in force on June 8, 1995, or that result from applications filed before that date "shall be the greater of" 17 years from grant or 20 years from filing. 35 U.S.C. § 154(c)(1). (Emphasis added). The wording of the URAA is unequivocal and mandates a 20-year-from-filing term in all cases where the patent was in force on June 8, 1995, and the 20-year term exceeds the term of 17 years from grant.[2/]

The Hatch-Waxman Act, enacted a decade earlier than the URAA, authorizes patent term restoration as partial compensation for the loss of effective patent life[3/] suffered by products, such as drugs, that are subject to FDA pre-

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[2/] As this Court has repeatedly held, Congress's use of the word "shall" establishes an inflexible requirement. *See, e.g., Fogarty* v. *Fantasy, Inc.*, 510 U.S. 524, n.11 (1994).

[3/] The term "effective patent life" refers to the period between FDA marketing approval for the product and the expiration of patent protection.

marketing regulatory review.[4/] 35 U.S.C. § 156. Section 156(a) states that eligible patents "shall be extended in accordance with this section from the original expiration date of the patent." (Emphasis added.) The Federal Circuit held that the term "'original expiration date' means no more than that the expiration date has not been extended under section 156(e)(1)." *See* 96-562 Pet. App. at 17a. The Federal Circuit's interpretation of this phrase is based directly on the language Congress added to Section 156(a)(2) when it enacted the URAA and is unambiguously supported by the legislative history of the Hatch-Waxman Act and the structure of 35 U.S.C. § 156.

When the Hatch-Waxman Act added Section 156 to Title 35, the term of patents, including those subject to Hatch-Waxman term restoration, was 17 years from grant. No

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[4/] The Hatch-Waxman patent term restoration periods do not compensate fully for the time lost in regulatory review, but merely "ameliorate the loss incurred when patent terms tick away while the patented product is awaiting [FDA] regulatory approval for marketing." *Unimed, Inc.* v. *Quigg*, 888 F.2d 826, 829, 12 U.S.P.Q.2d (BNA) 1644, 1647 (Fed. Cir. 1989).

extensions of that term were available for any patents other than pharmaceutical patents covering products whose marketing had been delayed by the FDA's regulatory processes. The phrase "original expiration date" in Section 156(a) simply served to distinguish the expiration date of a patent prior to consideration of the Hatch-Waxman Act from the expiration date inclusive of the Hatch-Waxman term restoration period.

This understanding is directly confirmed in a 1982 letter from the congressional draftsman of the phrase, then-Congressman Tom Railsback, to Bruce A. Lehman[5/] explaining why the phrase had been inserted into legislation that later became Section 156(a). *See* 96-562 Pet. App. at 15a-16a. This letter makes it clear that "original expiration date" refers to the date on which the patent would have

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5/ At the time, Congressman Railsback was the ranking minority member of the Subcommittee on Courts, Civil Liberties, and the Administration of Justice, which had substantive jurisdiction of the matter, and Mr. Lehman was counsel to the subcommittee. Mr. Lehman is now Commissioner of Patents and Trademarks and one of the cross-petitioners.

expired if not for the addition of a Hatch-Waxman restoration period.

> The insertion of 'from the original expiration date of the patent' . . . makes specific what was intended, namely, that the maximum extension . . . must be calculated from the original date of the patent. Thus, 2 five-year regulatory review periods for 2 different products under the same patent will result in only one extension from the original patent expiration date.

The single change that the URAA made in the Hatch-Waxman Act provides further direct support for the Federal Circuit's decision. The URAA amended 35 U.S.C. § 156(a)(2) by adding the underscored phrase to provide that a Hatch-Waxman extension may be granted as long as "the term of the patent has never been extended under subsection (e)(1) of this section." This change was needed because other provisions of the URAA for the first time[6/] permitted patent

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[6/] Prior to the enactment of the Hatch-Waxman Act in 1984, Congress added Sections 155 and 155A of the Patent Act, which provide statutory term extensions for a limited number of patents covering the food additive aspartame (Section 155) and the drug forane (Section 155A). *See United Sweetener USA, Inc.* v. *Nutrasweet Co.*, 760 F. Supp. 400, 419 (D. Del. 1991) (aspartame); 129 Cong. Rec. S. 6313 (daily ed. May 19, 1983) (statement of Mr. East) (forane).

term extensions for reasons other than FDA regulatory delay.[7/]

This amendment explicitly demonstrates the Congressional expectation that a patent term enlarged by the URAA could also benefit from Hatch-Waxman restoration under 35 U.S.C. § 156. The Hatch-Waxman restoration period of such a patent would be calculated from its "original expiration date," *i.e.*, the date the patent would expire if it were not extended pursuant to 35 U.S.C. § 156(e)(1). Thus, the language and structure of Section 156(e) as amended by the URAA also compels the Federal Circuit's interpretation of "original expiration date" (*see supra* p. 8) and its conclusion that respondents Merck and Schering are entitled to add Hatch-Waxman term restoration periods to the URAA-mandated 20-years-from-filing terms of their patents in suit,

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7/ The URAA authorized patent term extensions under 35 U.S.C. § 154(b)(1) to compensate for the loss of effective patent life resulting from interference delay and secrecy orders and authorized patent term extension under 35 U.S.C. § 154(b)(2) to compensate for delays due to appellate review of an adverse determination of patentability.

subject only to any applicable restrictions contained within the Hatch-Waxman Act itself.

3. The primary claim of the federal conditional cross-petitioners is that the Federal Circuit should have deferred to the interpretation of the statute by the PTO under *Chevron, U.S.A.* v. *Natural Resources Defense Council,* 467 U.S. 837 (1984). 96-562 Pet. App. at 14a.

This is plainly not a case where *Chevron* deference is appropriate. This case does not involve any issue relating to the PTO's particular expertise in an area in which Congress has granted it discretionary powers.[8/] *Compare Babbitt* v. *Sweet Home Chapter of Communities for a Great Oregon,* 115 S.Ct. 2407, 2418 (1995) (deference granted to agency with "broad discretion" in circumstances requiring "an expertise and attention to detail that exceeds the normal province of

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[8/] This case thus stands in sharp contrast to *Smiley* v. *Citibank (South Dakota) N.A.,* 116 S.Ct. 1730 (1996), for example, which concerned an interpretation of the banking laws by the Comptroller of the Currency, who "is charged with the enforcement of banking laws *to an extent that warrants the invocation of* [deference]." *Smiley,* 116 S.Ct. at 1733 (citations and internal quotation marks omitted) (emphasis added).

Congress"). This case does not involve the PTO's special expertise in scientific matters. Rather, it concerns the interpretation of the Patent Act. The federal judiciary has for two centuries been and remains the final arbiter of the meaning of the patent statue. The Federal Circuit has plainly been correct in repeatedly holding that no deference is due to the PTO's interpretations of the Patent Act. *See, e.g., Hoechst Aktiengesellschaft* v. *Quigg,* 917 F.2d 522, 526 (Fed. Cir. 1990) (no deference granted to PTO interpretation of ambiguous statutory language); *Glaxo Operations U.K., Ltd.* v. *Quigg,* 894 F.2d 392 (Fed. Cir. 1990) (in cases involving dissection of statutory language, courts are equally skilled in making interpretations).[2/]

[2/] It is worth noting that the Solicitor General did not seek a writ of certiorari in either of these cases. This is consistent with the position taken by the Solicitor General in the present case in opposing the petitions for certiorari in 96-562 and 96-575 and in other cases where the Federal Circuit refused to defer to the PTO's interpretation of the Hatch-Waxman Act. *See Ethicon, Inc.* v. *Quigg,* 849 F.2d 1422 (Fed. Cir. 1988) (certiorari not sought).

It is indicative of the PTO's limited role in interpreting the patent statute that Congress has granted the PTO only very limited rulemaking authority. As the Federal Circuit has held, the broadest of the PTO's rulemaking powers, found in 35 U.S.C. § 6(a), authorizes the Commissioner to promulgate regulations only "for the conduct of proceedings in the [PTO]," and does not grant authority to issue substantive rules. *See Ethicon, Inc.* v. *Quigg*, 849 F.2d 1422, 1425 (Fed. Cir. 1988). Accordingly, the PTO's statutory interpretation "cannot possibly have the force and effect of law." *Animal Legal Defense Fund* v. *Quigg,* 932 F.2d 920, 930, U.S.P.Q.2d at 1686 (Fed. Cir. 1991).

The PTO particularly lacks substantive rulemaking power over the Hatch-Waxman Act, for its role in the administration of the statute is purely clerical. The PTO receives applications for patent term restoration under the Hatch-Waxman Act, but is required to notify the FDA immediately. 35 U.S.C. § 156(d)(2)(A). The FDA

determines the period of regulatory delay that occurred and is authorized to hold a hearing and to resolve disputed issues as appropriate. 35 U.S.C. § 156(d)(2)(B). The PTO's role is limited to making certain arithmetic calculations after being informed of the length of the regulatory delay by the FDA.[10/] The calculation of the patent term restoration period is a purely mechanical exercise, involving addition and subtraction but no discretion.

4. In this case, it would be particularly inappropriate for the judiciary to defer to the PTO's interpretation of the Hatch-Waxman Act in light of the PTO's substantive flip-flop on the issue presented in this case. On

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[10/] The PTO calculates the length of the patent term restoration period by adding half the number of days that the patented product or method underwent clinical trials to the number of days the subsequently filed "New Drug Application" was pending before the FDA, subject to two limitations. First, the restoration period cannot exceed five years for patents issued subsequent to the enactment of the Hatch-Waxman Act; patents issued prior to the enactment of the Hatch-Waxman period generally are limited to a two-year extension. 35 U.S.C. § 156(g)(6). *Cf. Hoechst Aktiengesellschaft* v. *Quigg*, 917 F.2d 522 (Fed. Cir. 1990) (patent term restoration not limited by Section 156(g)). Second, the effective patent life cannot exceed 14 years. 35 U.S.C. § 156(c)(3).

March 27, 1995, after extensive consideration, the PTO published a "Proposed Determination" concerning the application of the URAA patent term transitional provision to patents in force on June 8, 1995, that qualified for term restoration under the Hatch-Waxman Act. 60 Fed. Reg. 15748 (Mar. 27, 1995). In this statement, the PTO expressed the view that the terms of such patents should be computed by adding the Hatch-Waxman restoration period to the end of the 20-year URAA term.

On June 7, 1995, the PTO completely reversed the position it had articulated ten weeks earlier and issued a so-called "Final Determination" announcing a revised view that holders of patents in force on June 8, 1995, and subject to Hatch-Waxman patent term restoration, "are entitled" to the longer term of either "(a) 17 years from grant, supplemented by the period of extension [under the Hatch-Waxman Act]," or "(b) 20 years from their relevant filing date," without any Hatch-Waxman restoration period. 60 Fed. Reg. 30069 (June

7, 1995). The PTO cited no new information that justified this about-face. *Id.* The PTO simply changed its mind.

5. Even if the PTO's interpretations of the Hatch-Waxman Act were generally entitled to deference under *Chevron*, the PTO's interpretation of "original expiration date" deserves no such deference because it cannot be reconciled with the language, history, and structure of the statute. The federal conditional cross-petitioners cannot explain away the Railsback letter, so they attempt to dismiss it as "superfluous."[11/] *See* 96-928 Cross. Pet. at 10. Nor can the federal cross-petitioners square the PTO's position with the sole amendment the URAA made to the Hatch-Waxman Act. If "original expiration date" meant the expiration date anticipated on the day the patent was granted, a patent extended under provisions other than 35 U.S.C. § 156(e)(1),

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11/ Recent amendments to the Hatch-Waxman Act, however, do not affect the historical import of the Railsback letter which, as the Federal Circuit recognized, helps explain the meaning of the phrase "from the original expiration date of the patent."

such as Section 154(b) as amended by the URAA, would be barred from also receiving Hatch-Waxman term restoration. Such an outcome is clearly contrary to the language of 35 U.S.C. § 156(a)(2).

Federal conditional cross-petitioners also claim that permitting the addition of Hatch-Waxman restoration periods to the URAA mandated 20-years-from-filing term could result in the violation of 35 U.S.C. § 156(c)(3), which places a 14-year limit on the effective patent life of a patent that has received Hatch-Waxman term restoration. *See* 96-728 Cross-Pet. at 10-11. They disregard the fact that the 14-year rule is one of the limitations on patent term restoration that is directly incorporated in the Hatch-Waxman Act and that the Federal Circuit held to be applicable to patents whose terms are enlarged by the transitional provisions of Section 154(c)(1).[12/] As the Federal Circuit recognized, nothing

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12/ The district court and Federal Circuit both held that the term of Merck's U.S. Patent No. 4,283,408 must be calculated so as not to exceed (continued...)

more than an arithmetical calculation is required to conform with the 14-year rule of section 156(c)(3). *See* 96-562 Pet. App. at 17a-18a.[13/]

6. The wholly distinct interpretation of the Hatch-Waxman Act urged by conditional cross-petitioner GPIA similarly lacks foundation in the statutory language. GPIA concurs with the Federal Circuit's interpretation of "original expiration date", but argues that permitting a Hatch-Waxman restoration period that was granted prior to June 8, 1995, to be added on to a URAA-mandated 20-years-from-application term would constitute a second application of a restoration

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[12/](...continued)
the 14-year limit on effective patent life set forth in 35 U.S.C. 156(c)(3). *See* 96-562 Pet. App. at 18a-19a; 96-575 Pet. App. at 33a.

[13/] Federal conditional cross-petitioners also raise the specter of the "problem of fitting together the different limitations on remedies during successive extensions," and suggest that the only way to address this problem is to prohibit in all cases the addition of a Hatch-Waxman term restoration period to a URAA-mandated 20-year-from-filing term. *See* 96-728 Cross-Pet. at 11, n. 9. Thus far, no reported case presenting such a problem has arisen, supporting the Federal Circuit's conclusions that "this problem is more illusory than real," and that "the majority of patents should not be denied extensions because of a mere possibility that special problems may arise in a few instances." *See* 96-562 Pet. App. at 19a-20a.

period in violation of Section 156(a).[14/] This argument, which was considered and rejected by the Federal Circuit, has no basis in the language of the statute and suffers from the additional flaw that it assumes that the URAA *sub silentio* withdrew previously certified Hatch-Waxman term restoration periods from pharmaceutical patents assigned the 20-years-from-filing term by Section 154(c)(1). If the URAA had been intended to affect patent term restorations in such a manner, Congress would have to have explicitly amended the language of Section 154 or Section 156. *See, e.g., Bristol-Myers Squibb* v. *Royce Laboratories,* 69 F.3d 1130, 1136 (Fed Cir. 1995), *cert. denied.,* 116 S.Ct. 754 (1996) (had Congress intended URAA to change Hatch-Waxman, it would have done so explicitly).

[14/] GPIA appears to call into question the mandatory nature of the transitional provision of the URAA, Section 154(c)(1), by claiming that the statute provides each patent "the option" of applying the 20-year-from-application patent term. 96-761 Cross. Pet. at 9 (emphasis added). As discussed above, Section 154(c)(1) is clearly mandatory. *See supra* p. 7.

CONCLUSION

The conditional cross-petitions in 96-728 and 96-761 for a writ of certiorari should be denied.

Respectfully submitted,

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